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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA VA 22314

In re Application of	:
Matsui et al.	:
Serial No.: 09/462,472	: PETITION DECISION
Filed: January 14, 2000	:
Attorney Docket No.: 0010-1075-0 PCT	:

This is in response to the renewed petition under 37 CFR 1.144, filed April 20, 2006, requesting withdrawal of an alleged improper election of species requirement of claim 13.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 371 on January 14, 2000, and contained claims 1-13.

In a first Office action, mailed March 28, 2001, the examiner set forth a restriction requirement under 35 U.S.C. 121 and 372, as follows:

Group I, claim 1, drawn to a microorganism belonging to the genus *Escherichia* and having purine nucleoside-producing ability.

Group II, claim 2, drawn to a microorganism belonging to the genus *Escherichia* which has acquired a purine nucleoside-producing ability because of an increase of an activity of an enzyme involved in purine nucleoside biosynthesis.

Group III, claim 3, drawn to a microorganism belonging to the genus *Escherichia* which has acquired a purine nucleoside-producing ability because of an increase of an expression amount of a gene for an enzyme involved in purine nucleoside biosynthesis.

Group IV, claims 4, 5, and 8, drawn to a microorganism belonging to the genus *Escherichia* which has acquired a purine nucleoside-producing ability because of deregulation of control of an enzyme involved in purine nucleoside biosynthesis.

Group V, claims 9 and 10, drawn to a microorganism belonging to the genus *Escherichia* which has acquired a purine nucleoside-producing ability because of blockage of a reaction branching from purine nucleoside biosynthesis and leading to another metabolite.

Group VI, claims 11 and 12, drawn to a microorganism belonging to the genus *Escherichia* which is enhanced in purine nucleoside-producing ability by weakening of incorporation of a purine nucleoside into cells of the microorganism.

Group VII, claim 13, drawn to a method for producing a purine nucleoside by fermentation comprising culturing a microorganism belonging to the genus *Escherichia*.

In justifying the reasons for the lack of unity, the examiner reasoned that Groups I-VII lack "the same or corresponding special technical feature". Specifically, the special technical feature of applicants' invention is the purine nucleoside producing ability of a microorganism belonging to the genus *Escherichia*, and that Neuhard et al. teach that *Escherichia coli* has a biosynthetic pathway to produce purine nucleosides.

In claim 9, the examiner required an election of a single disclosed species of enzyme because the species of enzymes set forth were not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows: monophosphate synthase, purine nucleoside phosphorylase, adenosine deaminase, inosine-guanosine kinase, guanosine monophosphate reductase, 6-phosphogluconate dehydrase, phosphoglucose isomerase, adenine deaminase, and xanthosine phosphorylase.

On March 24, 2001, applicants filed a Response and elected Group VII, claim 13, with traverse. In addition, applicants elected, with traverse, phosphoglucose isomerase as a single disclosed species of an enzyme. Applicants argued the restriction on the basis that a search of all the claims would not impose a serious burden on the Office, and the species claimed have a common activity and belong to a recognized class of chemical compounds and should therefore be examined together.

The examiner mailed a non-final Office action to applicants on August 14, 2001, in which the examiner made the lack of unity final and responded to applicants' traversal by pointing out to applicants that a search of all the inventions in the patent literature and the non-patent literature cannot be made without serious burden because the inventions require separate searches that have different limits, boundaries, scope, and subject matter. The examiner also pointed out that the enzymes catalyze different reactions, are different chemical entities, and require separate searches. The examiner also rejected claim 13 under 35 USC 102 (b) as being anticipated by Okumura et al which teach the mutant *Escherichia coli* that produces the purine xanthosine. Claims 1-12 were withdrawn from consideration.

The reply to this Office action was filed by applicants on December 14, 2001 with an amendment to claim 13, and addition of method claims 14-26. The traversal set forth in applicants previous response was not continued in this reply.

The examiner issued a final Office action on March 13, 2002 rejecting claims 13-26 under 35 USC 112, first paragraph and rejecting claims 13-16 and 22-26 under 35 USC 112, second paragraph. Applicants' amendment necessitated these new grounds and the examiner properly made the Office action final.

Applicants filed a Notice of Appeal on September 13, 2002, followed by a request for continued examination (RCE) on March 12, 2003, and cancelled claims 23, 24, and 26, and added claim 27.

The examiner mailed a non-final Office action to applicants on May 6, 2003 wherein claims 13-22 and 25 were objected to for reciting non-elected subject matter, claims 14-22 and 25 were rejected under 35 USC 112, second paragraph, for indefiniteness, and claim 27 was objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim.

Applicants filed a request for reconsideration of the non-final Office action of May 6, 2003 on August 6, 2003. The traversal set forth in applicants' response of March 22, 2004 was not continued in this reply.

The examiner mailed a Final Office action to applicants on October 21, 2003 wherein claims 13-22 and 25 were objected to for reciting non-elected subject matter, claims 14-22 and 25 were rejected under 35 USC 112, second paragraph, for indefiniteness, and claim 27 was objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim.

Applicants filed a Notice of Appeal on March 22, 2004. Also on that date, applicants filed a response to the Final Office action. Applicant argued that the PCT administrative instructions in the MPEP, Annex B, Part (f), the requirement of the same special technical feature as defined in PCT Rule 13.2 is considered to be met when the alternatives of a Markush group are of similar nature. They argued that the enzymes have a common activity because they catalyze the reaction branching from the purine nucleoside biosynthesis. Further, they argued that the Markush group members all are enzymes and thus are a recognized class of compounds. Applicants further argued that the examiner would not be burdened by further searching. Further they noted, that the International Searching Authority had already examined all of the claims, including the species in question. The applicants then directed the examiner to MPEP 803.02 and stated that the examiner must examine all of the members together. Applicants also noted that the elected species (phosphoglucose isomerase) was allegedly indicated as allowable. Therefore applicants concluded that the examiner is compelled to expand the scope of the search to embrace all of the non-elected species of claim 13.

On March 22, 2004 applicant filed a petition to the Commissioner under 37 C.F.R. 1.144 to review and withdraw the restriction requirement of June 21, 2001. The applicants also requested that the examiner expand the scope of examination to include the non-elected members of the Markush group of claim 13.

On November 16, 2004, the Office issued a decision of the petition which concluded that the lack of unity requirement was modified to rejoin claims 1-12 as these claims have the special technical feature of *Escherichia* that is already known with the property of producing purine nucleoside as taught by Neuhard et al (of record). The new lack of unity requirement was as follows:

Group I, claims 1-12, drawn to a microorganism belonging to the genus *Escherichia* and having purine nucleoside-producing ability.

Group II, claim 13 (and newly added claims 14-27), drawn to a method for producing a purine nucleoside by fermentation comprising culturing a microorganism belonging to the genus *Escherichia*.

The inventions listed as Group I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of applicants' invention is the purine nucleoside producing ability of a microorganism belonging to the genus *Escherichia*. Neuhard et al (of record) teach that *Escherichia coli* has a biosynthetic pathway to produce purine nucleosides. Since applicants' inventions do not contribute a special technical feature when viewed over the prior art, they do not have a single general inventive concept, and therefore lack unity of invention.

Regarding the election of species requirement, applicants argued that the examiner improperly required an election of a single disclosed species from members of a Markush group of enzymes. Applicants argued that the election of species requirement was improper because the requirement of the same special technical feature as defined in PCT Rule 13.2 is considered to be met when the alternatives of a Markush group are of similar nature, as in this case, because they catalyze the reaction branching from the purine nucleoside biosynthesis. Applicants also argued that the compounds of the Markush group belong to a recognized class of chemical compounds in the art to which the invention pertains. Applicants further argued that the examiner had misapplied the examination standard provided by MPEP 803.02 for Markush type claim practice because the members of the Markush group are sufficiently few in number and are so closely related so as not to constitute a serious search burden for the examiner, and that the examiner should therefore expand the search to embrace the non-elected species. Applicants' arguments are not persuasive as the examination standard provided by MPEP 803.02 does not apply to PCT. According to Administration Instructions, Annex-, Part B, the species election between the enzymes can be maintained even though they all belong to a recognized class of chemical compounds because all the enzymes claimed do not fulfill the following criteria:

- all of the enzymes do not share a common structure and at least one Markush alternative is not novel over the prior art. Specifically, Seeger et al. (copy enclosed) teach the enzyme xanthosine phosphorylase as claimed and Mori et al. (copy enclosed) teach the enzyme inosine-guanosine kinase as claimed.

On October 20, 2005, the Office issued a non-final rejection reopening the prosecution of the case. While the Office action made no mention of the restriction requirement, election of species or the petition decision, it did re-apply art rejections in the case. The art rejections were under 35 USC 103. Claims 1-12 remained withdrawn as non-elected.

The renewed petition to the Commissioner under 37 C.F.R. 1.144 to review and withdraw the election of species requirement filed June 21, 2001, was filed on April 20, 2006, along with a reply to the Office action.

DISCUSSION

The application, file history and petition have been considered carefully. In the petition, Applicants request consideration of all of the enzymes in claim 13.

This application was filed under 35 U.S.C 371 and as such the requirements for Unity of Invention are as follows: An international or a national stage application is considered to have unity of invention where there exists a "special technical feature" that defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See PCT Rule 13.2;

PCT 13.2 Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

See Annex B, Part 2 of the PCT Administration Instructions

MPEP 1850 states *Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims and*

(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims;
(ii) If however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on the claim need to be carefully considered. If there is no link remaining an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised. See ANNEX B: Unity of Invention Part 1 "Instructions Concerning Unity of Invention" MPEP AI-6 (Rev. 1. Feb. 2003).

37 CFR 1.475(b)-(d) provides guidance for treatment of second and subsequent products and methods.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(2) A product and process of use of said product; or

Applicants' arguments have been fully considered. The election of species requirement was traversed on the grounds that examination on the merits of the entire application would not present a serious burden upon the Examiner and, as such, the examiner must examine it on the merits, even though it allegedly includes claims to distinct or independent inventions. However, this is not a criterion for lack of unity. Burdensome search is a requirement for restrictions and election of species under 35 USC 121. The criteria for lack of unity are a special technical feature and unity of invention. Applicants further note that the International Searching Authority did not take the position that unity of invention was lacking in the International application and examined all of the claims together. However, this argument is not well taken as lack of unity is reviewed at each stage of prosecution.

Further, applicants argue that the examiner improperly required an election of a single disclosed species from members of a Markush group of enzymes. Applicants argue the election of species requirement was improper because the requirement of the same special technical feature as defined in PCT Rule 13.2 is considered to be met when the alternatives of a Markush group are of similar nature, as in this case, because they catalyze the reaction branching from the purine nucleoside biosynthesis. Applicants also argue that the compounds of the Markush group belong to a recognized class of chemical compounds in the art to which the invention pertains. Applicants further argue that the examiner has misapplied the examination standard provided by MPEP 803.02 for Markush type claim practice because the members of the Markush group are sufficiently few in number and are so closely related so as not to constitute a serious search burden for the examiner, and that the examiner should therefore expand the search to embrace the non-elected species.

Applicants' arguments are not persuasive as the examination standard provided by MPEP 803.02 does not apply to PCT. According to Administration Instructions, Annex-, Part B, the species election between the enzymes can be maintained even though they all belong to a recognized class of chemical compounds because all the enzymes do not share a common structure and at least one Markush alternative is not novel over the prior art. Specifically, Seeger et al. (copy enclosed) teach the enzyme xanthosine phosphorylase as claimed and Mori et al. (copy enclosed) teach the enzyme inosine-guanosine kinase as claimed.

Further, there is no special technical feature in the application since a microorganism belonging to the genus *Escherichia* and having purine nucleoside-producing ability was known at the time the invention was made. Evidence of this is seen in the art rejections of record, namely, Mascarenhas et al. as cited on page 5 of the Office action filed, October 20, 2005. Mascarenhas in the abstract clearly teaches deletion of the structural gene for phosphoglucose isomerase (pgi) of *E. Coli* (*Escherichia coli*).

Thus, since the examiner has established that there is no special technical feature since a microorganism belonging to the genus *Escherichia* and having purine nucleoside-producing ability was known at the time the invention was made and since there is art on the record to reject the claim in question (claim 13) and the specific species, namely phosphoglucose isomerase, then the election of species is proper. Even though the International Searching Authority at the time the Search Report was done did not apply a lack of unity, lack of unity does exist since there is no special technical feature and thus lack of unity must exist. Therefore, the

examiner has established that election of species is proper. If the examiner could not find art on the elected species then the examiner would have had to move to another species to examine but the examiner did in fact find art to reject the elected species, namely, phosphoglucose isomerase.

Thus, the examiner was correct in applying and maintaining the election of species requirement in question.

DECISION

The petition is **DENIED**.

Since the Petition has been **DENIED** and the applicant has already submitted a response to the prior Office action, the application will be returned to the examiner for the next appropriate Office action.

Should there be any questions about this decision please contact Marianne C. Seidel by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 571-273-8300.



Bruce M. Kisliuk
Director, Technology Center 1600